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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,327	06/28/2004	Kenichi Sato	1029650-000152	8954
21839	7590	10/22/2007	EXAMINER	
BUCHANAN, INGERSOLL & ROONEY PC			WIEST, PHILIP R	
POST OFFICE BOX 1404				
ALEXANDRIA, VA 22313-1404			ART UNIT	PAPER NUMBER
			3761	
			NOTIFICATION DATE	DELIVERY MODE
			10/22/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com  
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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/500,327	SATO ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Phil Wiest	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 October 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3 and 5 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3 and 5 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 March 2007 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/4/07 has been entered.

### ***Response to Amendment***

2. In the amendment filed 10/4/07, applicant amended claim 1 and canceled claim 6. Claims 1-3 and 5 are currently pending.

### ***Claim Objections***

3. Claim 1 is objected to because of the following informalities: Line 6 of claim 1 states that a connecting tube is connected liquid-tightly to the container, but does not disclose which container it is connected to. For the purposes of examination, the examiner has assumed that the tube may be connected to any container. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

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4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 1-3, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Sioufi (US 4,938,758) in view of Kwon et al (US 6,340,770), and further in view of Howell et al. ("*Intraperitoneal cisplatin with systemic thiosulfate protection*").

6. With respect to Claim 1, Al-Sioufi discloses a blood bag system comprising a container 10 holding an inactivator 12, a container 2 holding an anticoagulant 9, a connecting tubes 5 connected liquid-tightly between the containers (2, 12), a plurality of additional containers (3, 4) that are capable of holding an neutralizing agent, and a tube (5, 6, 7) that is capable of introducing a fluid to container 2 from containers 3 and 4.

See Figures 1 and 3. Al-Sioufi further discloses that the inactivator 12 is to be buffered (i.e. neutralized) to the pH of collected blood (about 6.5-7.4) (Column 7, Line 64 through Column 8, Line 8). Al-Sioufi, however, does not specifically disclose that the inactivator comprises a platinum compound, or that the inactivator is neutralized by an separate neutralizing agent.

7. Kwon et al. (hereafter Kwon) disclose a platinum complex capable of binding to nucleic acid of the microorganism or an aquo complex of the platinum compound (Column 1, Lines 52-55 and Column 35, Lines 13-67). Furthermore, Kwon discloses that the platinum compound is capable of inactivating a pathogenic microorganism such as DNA (Column 1, Lines 52-55). Regarding Claim 2, Kwon discloses that the platinum complex can be either cisplatin or carboplatin. The use of these compounds as inactivators is well known in the art of blood purification (Column 1 Lines 43-54).

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Regarding Claim 3, Kwon discloses that the aquo complex of the platinum compound comprises a dihydroxo complex (Column 35, Lines 13-67). It would have been obvious to one skilled in the art at the time of invention to combine the blood bag system of Al-Sioufi with the platinum complex of Kwon in order to provide proper housing in which blood can react with said platinum compound.

8. Howell et al. (hereafter Howell) discloses a method for treating tumors comprising the use of the use of a cisplatin inactivator and sodium thiosulfate neutralizer to neutralize the cisplatin. The addition of thiosulfate to the cisplatin solution enables the concentration of cisplatin to be safely escalated to 270 mg/m<sup>2</sup> body surface area. Because pathogen inactivation requires higher concentration of inactivator than cancer inactivation, this would allow pathogens to be inactivated in a more effective way while keeping the patient safe. Therefore, it would have been obvious to one skilled in the art at the time of invention to add a neutralizing agent such as sodium thiosulfate to one of the additional bags of Al-Sioufi such that the platinum compound may be neutralized when it is introduced to the blood. The neutralization of the platinum compound will allow the amount of cisplatin used to be increased, thereby improving the efficiency of a pathogenic or cancer inactivation.

#### ***Response to Arguments***

9. Applicant's arguments with respect to claims 1-3 and 5 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that Kwon does not disclose the use of cisplatin to inactivate microorganisms. However, this argument is broader than applicant's claims. Cisplatin is **fully capable** of inactivating microorganisms as well as hindering the growth of cancer cells, as supported by applicant's specification. Because Kwon teaches that cisplatin is capable of inactivating normal cells such as DNA type viruses (see rejection), there is sufficient motivation to combine the references.

Additionally, Howell clearly discloses the use of sodium thiosulfate as a neutralizing agent. Al-Sioufi provides motivation for this in stating that it is desirable to neutralize the inactivator to a pH of approximately 7.0 in order to reduce the side effects of the treatment.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW  
10/12/07

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

